THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Ream, et al.
Appl. No.:	09/990,628
Conf. No.:	4209
Filed:	November 13, 2001
Title:	OVER-COATED CHEWING GUM FORMULATIONS
Art Unit:	1615
Examiner:	J. Venkat
Docket No.:	112703-203

Commissioner for Patents
P.O. Box 1450
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APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated June 9, 2008 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit that the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated August 22, 2007 as noted in Appellants' Appeal Brief filed on March 3, 2008, for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 9-26 be reversed.

II. THE REJECTION OF CLAIMS 9-26 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCE

Appellants respectfully request that the Board reverse the rejections of Claims 9-26 under 35 U.S.C. §103(a) because *Cherukuri* and *Stahl* fail to disclose or suggest all of the claimed elements of the present invention.

Independent Claims 9 and 18 recite, in part, a product comprising a gum center and a coating comprising at least 50% by weight of the chewing gum product. An advantage of the present claims is to provide a product that can deliver medicaments to an individual that provides increased absorption and bioavailability (*e.g.*, through the oral mucosa) as compared to medicaments that are designed to be absorbed in the GI tract.

Indeed, Appellants have surprisingly found that administering medicament through chewing, as opposed to swallowing, results in faster drug absorption through the oral mucosa. In this manner, an increase in the absorption of the medicament is achieved as well as an increase in the bioavailability of the drug as compared to typical oral administration. By using such a high coating level (*i.e.*, at least 50% by weight of the product), the level of medicament or agent in the coating can be selected so as to create, when the product is chewed, a sufficiently high concentration of the medicament or agent in the saliva. The medicament in the saliva can then pass more readily through the oral mucosa in the buccal cavity, which favors faster drug absorption over oral ingestion. Appellants have carefully researched the desirability, applicability and levels of the coating and medicament for such oral administration.

In contrast, *Cherukuri* and *Stahl* fail to disclose or suggest a product comprising a gum center and a coating comprising at least 50% by weight of the chewing gum product as is required, in part, by independent Claims 9 and 18. Instead, *Cherukuri* is directed to a so-called "one step" or "one syrup" method for providing a sugarless coating on a solid center, which includes applying alternating layers of coating syrup and dusting mix. See, *Cherukuri*, col. 2, lines 14-30. As a result, rather than teaching overall coating levels, *Cherukuri* emphasizes the components of the coating syrup and dusting mix as well as specific ingredient percentages within the coating syrup and dusting mix. See, *Cherukuri*, col. 2, lines 40-55 and col. 3, line 51

to col. 4, line 4. If fact, none of the weight percentages disclosed teach a coating comprising at least 50% by weight of the overall product. Therefore, as admitted by the Examiner in the Office Action dated August 22, 2007, *Cherukuri* fails to disclose or suggest a coating comprising at least 50% by weight of the chewing gum product as required, in part, by Claims 9 and 18. Instead, the highest, and only, coating level disclosed in *Cherukuri* is 35 weight percent of the coated chewing gum tablet. See, *Cherukuri*, col. 4, lines 29-34 and col. 7, lines 13-19.

Similarly, *Stahl* is directed, at least in part, to a coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substances in solid form. See, *Stahl*, Abstract. However, at no place in the disclosure does *Stahl* disclose or even suggest any weight percent of a coating with respect to the core of chewing gum, let alone a coating comprising at least 50% by weight of the overall product. Indeed, because *Stahl* fails to disclosure or even suggest such a percentage, the Examiner merely relies upon *Stahl* for arguably teaching a medicament in the coating along with a sweetener.

In the Examiner's Answer, and despite the Examiner's admissions that neither *Cherukuri* nor *Stahl* disclose or even suggest a coating comprising at least 50% by weight of the chewing gum product, the Examiner maintains that column 4, lines 29-34 of *Cherukuri* teaches one skilled in the art how to obtain at least 50% by weight coating since *Cherukuri* clearly teaches that 10-12 coats of coating syrup and 7-9 coats of dusting mix are required for 35% by weight of chewing gum. The Examiner asserts that one skilled in the art, by routine experimentation, could calculate the number of sugar coatings and dusting mixes required to achieve the at least 50% by weight coating of the present claims. However, Appellants respectfully disagree and submit that one having skill in the art would have no reason, in view of *Cherukuri*, to increase the coating level from a typical level of 35% to the presently claimed coating level of at least 50%.

As stated in the Appeal Brief, it is not commonplace for chewing gum products to have coatings that include an increased coating level of at least 50% by weight coating. See, specification, page 13, lines 27-28. This is further supported by the inability of the Examiner to locate any prior art that discloses same. As a result, it is essential for the Examiner to establish a sufficient reason to achieve such a high level of coating. Further, as it is not commonplace for chewing gum products to have increased levels of coatings of at least 50% by weight coating, it must also follow that it is even less common and, in fact in this case, entirely novel to provide active ingredients or medicaments at increased levels in the already increase coating level of at

least 50% by weight coating. The benefits of using such a high coating level (*i.e.*, at least 50% by weight of the product) have been discussed at length throughout the prosecution of this application and in Appellants' Appeal Brief.

Moreover, *Cherukuri* already teaches a specific coating procedure and coating level (35%) for coated chewing gum and fails to teach that the weight percentage of coating can vary from this established level for coated chewing gum. Instead, *Cherukuri* teaches that the number of applications can vary based on factors such as amount of solids in the coating syrup. Using the above teachings in *Cherukuri*, if the solids level in a coating syrup is low, the number of coating syrup applications can increase to meet the 35 weight % established form coating in a coated chewing gum. However, this still does not teach or provide any reason for increasing the overall coating weight percentage above the 35% that *Cherukuri* establishes for a coated chewing gum. *Cherukuri* also fails to teach medicament or agent use in the coating as a reason for varying the number of coating syrup/dusting mix applications. Therefore, *Cherukuri* provides no reason why one skilled in the art would increase the weight percentage of coating in a chewing gum from 35% to at least 50%.

In sum, *Cherukuri* and *Stahl* fail to disclose or suggest every element of the present claims and fail to even recognize the advantages, benefits and/or properties of a consumable product having a coating comprising at least 50% by weight of the product in accordance with the present claims.

For at least the reasons discussed above, the cited reference does not teach, suggest, or even disclose all of the elements of Claims 9-26, and thus, fail to render the claimed subject matter obvious for at least these reasons. Therefore, Appellants respectfully submit that Claims 9-26 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

Accordingly, Appellants respectfully request that the obviousness rejection with respect to Claims 9-26 be reconsidered and the rejection be withdrawn.

III. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the obviousness rejections with respect to Claims 9-26.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-203 on the account statement.

Respectfully submitted,

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Dated: August 8, 2008